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(57) Abstract

An inflatable balloon (10) is placed in the stomach, to treat obesity by reducing appetite for food. The balloon can be inflated by liquid delivered to it by a supply line, (Fig. 1), by the gaseous reaction product of a chemical reaction within the ballon (Fig. 3) or by absorption of liquid through its semi-permeable wall (Fig. 4). The balloon is preferably piriform or ellipsoidal. Delivery to the stomach of the balloon (10) and supply line (13) by an overtube (14) with a closed smooth end presentation (16) is achieved by providing a fully-bounded side slit (17) in the overtube (14) from which the balloon (10) exists the overtube during its inflation. The balloon valve (11) and supply line (13) are preferably a mutual friction fit, enabling traction on the supply line alone to leave the balloon free-floating in the stomach following its inflation.

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ARTIFICIAL BEZOAR

BACKGROUND OF THE INVENTION

Field of the Invention

The present invention relates to artificial bezoars and to apparatus for treating obesity which includes an artificial bezoar.

Discussion of the Prior Art

There have been a number of proposals to treat obesity by use of an artificial bezoar. See, for example, GB-2139902-A, EP-0086862-A, W080/00007 and 83/02888 and US4133315 and 4416267. One problem is to find a bezoar construction which retains its properties over an extended period of time while in residence in the stomach. Thus, an inflatable latex rubber balloon bezoar has been tried, but it was found that it tended to deflate over a relatively short period. A second problem is how to achieve oral insertion without damaging oesophageal tissue, and yet another problem is to achieve reliable inflation of a balloon after it has been introduced into the stomach cavity.

EP-0137878-A discloses apparatus which includes a stomach tube which contains an uninflated stomach balloon at a leading end of the stomach tube. This one end of the stomach tube is slit to the end of the tube, and the slit sides of the tube are laced together until the balloon is due to be inflated, when the lacing is removed. The

arrangement is relatively complicated, and the slit and laced end of the stomach tube has a roughness of surface which makes it unattractive for oral introduction to the stomach.

It is one object of the present invention to provide ways of overcoming the above-mentioned difficulties.

SUMMARY OF THE INVENTION

According to a first aspect of the present invention there is provided apparatus for treating obesity in a patient, the apparatus comprising a valved balloon for placement in the stomach of the patient and a fluid supply line having a far end detachably connected to the valve and a near end for connection externally of the patient to a fluid supply means for inflation of the balloon within the stomach, the supply line and the balloon prior to its inflation being accommodated within an overtube by which the balloon may be introduced orally into the stomach, the uninflated balloon being housed adjacent a leading end of the overtube, characterised in that the leading end of the overtube is closed and has a smoothly convex shape, and in that the cylindrical wall of the overtube adjacent said closed leading end includes an elongate fully-bounded aperture which extends lengthwise of the overtube and through which the balloon exits the overtube in the course of its inflation.

It is convenient to use as the overtube a flexible tube of a length in a range from 60 to 70 cms and a diameter in the range of from 1 to 1.5 cms similar to the tubes which are currently employed for gastric aspiration. The tip of the overtube is smooth and the inflating balloon exits through a lengthwise sideways-facing slit, so that the leading end of the overtube is easily introduced into the stomach and removed from it.

Preferably, there is spacing, between the outside diameter of the fluid supply line and the inside diameter of the overtube, to allow for relative longitudinal movement of the supply line, as necessary, along the internal lumen of the overtube. At the proximal end of the supply line there may be a standard Luer fitting for convenient attachment to a fluid source, which may be, for example, a syringe or an infusion line. Conveniently, the leading i.e. distal end is tapered for insertion into a correspondingly shaped female element of the valve of the balloon for the purpose of inflation, and subsequent detachment by traction to leave the balloon free-floating in the stomach.

Construction of the balloon from acid-resistant material is essential. It has been found that latex and some other rubbers or plastics are rapidly destroyed by the acid and pepsin which are present in the gastric juice. Silicone rubber has, however, been found to be suitable.

Preferably, the balloon is of pear (piriform) or oval (ellipsoidal) shape and is of elastomeric material. Preferably, it is inflated through a self-sealing valve located at a narrow end of the balloon. A balloon of ellipsoidal or piriform shape complies more easily with the natural pear shape of the human stomach than does a spherical balloon, and without producing undue dilation of the central stomach. Such dilation could produce abdominal discomfort around the widest parts of the balloon and impair the process of gastric emptying. In addition the longitudinal axis of the balloon will tend to align with the longitudinal axis of the stomach, and the balloon will be more likely to occupy space in the more proximal stomach where the satiety centre is thought to lie. A balloon of the preferred shape will furthermore leave less of the reservoir capacity of the stomach available for food storage and will have a greater flexibility for increased capacity without producing undue gastric distortion, stretching tension or

mucosal damage.

The balloon should be adapted to contain about 500 millilitres of liquid under inflation in normal use, but preferably it should be able when required to accommodate liquid up to an amount of 1 litre or more. The wall thickness should be as small as possible for passage along the oesophagus whilst deflated but large enough to withstand the long-term, potentially damaging, effects of intragastric acid, food products and pressure effects of the vigorously contracting stomach. Preferably, the chosen wall thickness is the optimum compromise between these opposed requirements.

The balloon valve should be competent and continent against fluid leakage over a relatively long period of time, that is, a period of months, say six months. Preferably, it is constructed of the same material as the balloon for ease of manufacture and it should add to the weight of the balloon as little as possible.

According to a second aspect of the present invention there is provided an artificial bezoar being a capsule adapted to be swallowed or otherwise delivered orally to the stomach the capsule comprising a resilient balloon arranged in a compact, deflated disposition and containing a substance which is capable of undergoing a change of volume of at least two decimal orders of magnitude to inflate the balloon in the stomach.

One way in which the substance is capable of undergoing such a change of volume is for it to undergo a chemical reaction which results in the evolution of gas. Preferably, the gas should be one which does not harm the human body. Carbon dioxide is considered acceptable. For example, the capsule might contain a substance such as sodium bicarbonate which reacts with hydrochloric acid to generate gasesous

carbon dioxide. The acid could be introduced into the capsule by injection with a needle through a self-sealing wall area of the capsule, and the capsule swallowed immediately thereafter so that inflation of the balloon takes place in the stomach. Tube delivery to the stomach, instead of swallowing, would avoid possible blockage of the oesophagus as a result of premature balloon inflation.

To achieve an inflated volume of 500 mls by chemical reaction between hydrochloric acid and sodium bicarbonate requires approximately 1 g of sodium bicarbonate and 1 ml of N/10 hydrochloric acid.

An alternative possibility is to form the balloon from a material which is a semi-permeable membrane, and to enclose within the balloon a small amount of a substance which has the capacity to absorb, in large quantity, the water or gastric fluid which passes inwardly into the balloon through the semi-permeable membrane wall. It is thought that certain cellulose materials have the necessary properties. Conveniently, the balloon are packaged in a tight and compact disposition within a capsule which is adapted to be swallowed and is formed from a material which dissolves in the stomach to allow contact of the gastric fluids with the semi-permeable membrane balloon.

BRIEF DESCRIPTION OF THE DRAWINGS

In the accompanying drawings:

Figure 1 is a perspective view of a first embodiment of the invention;

Figure 2 is a scrap section along the longitudinal axis of the valve of the balloon of Figure 1;

Figure 3 is a side view, partly in section, of a

capsule which is a second embodiment of the invention; and

Figure 4 is a view like Figure 3, of a third embodiment.

PREFERRED MODES FOR CARRYING OUT THE INVENTION

Referring to Figure 1 and 2, a balloon 10 of silicone rubber has a valve 11 which accommodates the distal end 12 of a liquid supply line 13 which extends the full length of an overtube 14 to a liquid supply syringe 15. For introduction of the balloon 10 to the stomach of a patient, it is packed in the overtube 14 adjacent its closed and smoothly rounded distal (leading) end 16. After the distal end 16 of the overtube 14 has been passed down the oesophagus to the stomach, liquid may be delivered down the supply line to the balloon 10 to inflate it and cause it to exit the overtube 14 through an elongate, fully bounded aperture 17 in the cylindrical wall of the overtube 14 adjacent its distal end 16.

Figure 2 shows the construction of the valve 11. A hollow stem 20 bonded to the wall of the balloon 10 has a closed end 21 but an aperture 22 in its cylindrical wall 23. A sealing sleeve 24 overlies the aperture 22 and allows liquid to flow from inside the stem 20 to inside the cavity of the balloon 10 but not in the opposite direction. In other embodiments, the sleeve 24 could be a skirt around the stem 20 or a flap over the aperture 22.

If manual deflation of the balloon is required, the valve 11 can be so designed that manual squeezing of it will allow fluid to escape through the valve.

The distal end 12 of the supply line 13 is a firm friction fit in the stem 20. When the balloon has been inflated, tension on the supply line 13 will bring the

balloon up against either the overtube or the oesophageal sphincter, and further pulling of the supply line will draw the distal end thereof out of the hollow stem 20 of the valve 11 and allow the balloon to float freely within the stomach. If the supply line is made of resilient material, tension on it will tend to reduce its diameter. This effect should assist its disengagement from the stem 20 of the valve 13.

The capsule 30 of Figure 3 contains a tightly-packed balloon 31 with a neck 32 bonded to an open end 33 of a short length of tube 34. The other end 35 of the tube 34 is closed by a self-sealing elastomeric plug 36 of a material which resists chemical attack by stomach acids but allows passage of a syringe needle and closes up after passage of the needle. Within the tube 34 is contained a quantity 37 of a substance which can undergo chemical reaction to generate gas to fill the balloon 31. For example, 500 ml of CO_2 is generated by injecting 1 ml of N/10 Hydrochloric acid into 1 g of sodium bicarbonate. Inflation of the balloon 31 causes the capsule 30 to fall away. The capsule is swallowed immediately after injection of the acid, and can be made of a material which gradually dissolves or is consumed in the stomach.

In an alternative embodiment which avoids the risk of inflation in the oesophagus, illustrated in Figure 4, the balloon 40 is made of a material through which water may pass to a medium 41 within the balloon 40 which swells up on contact with the water. One such medium is a cellulose material. The balloon 40 is contained in a two-part capsule 42 which dissolves in the stomach or is consumed by it.

CLAIMS

1. Apparatus for treating obesity in a patient, the apparatus comprising a valved balloon (10) for placement in the stomach of the patient and a fluid supply line (13) having a far end (12) detachably connected to the valve (11) and a near end for connection externally of the patient to a fluid supply means (15) for inflation of the balloon within the stomach, the supply line and the balloon prior to its inflation being accommodated within an overtube (14) by which the balloon may be introduced orally into the stomach, the uninflated balloon being housed adjacent a leading end (16) of the overtube, characterised in that the leading end of the overtube is closed and has a smoothly convex shape, and in that the cylindrical wall of the overtube adjacent said closed leading end includes an elongate fully-bounded aperture 17 which extends lengthwise of the overtube and through which the balloon exists the overtube in the course of its inflation

2. Apparatus as claimed in claim 1 characterised in that the balloon is made of silicone rubber.

3. Apparatus as claimed in claim 1 characterised in that the balloon includes a self-sealing one-way inflation valve (11) with which the far end (12) of the supply line is a friction fit.

4. Apparatus as claimed in claim 3 characterised in that the valve (11) lies inside the envelope of the balloon and has a hollow stem (20) which extends from the skin of the

balloon radially inwardly relative to the balloon skin, and the far end (12) of the supply line (13) extends into the hollow stem.

5. Apparatus as claimed in claim 4 characterised in that the valve includes a flexible valve member (24) which overlies a valve aperture (22) in the radially outer cylindrical surface (23) of the valve stem (20).

6. Apparatus for treating obesity comprising an artificial bezoar characterised in that it is constituted by a capsule (30) comprising a resilient balloon (31) arranged in a compact, deflated disposition and containing a substance (37) which is capable of undergoing a change of volume of at least two decimal orders of magnitude to inflate the balloon in the stomach.

7. Apparatus as claimed in claim 6 characterised in that said substance (37) is one which reacts with another substance to yield as reaction product a gas which serves to inflate the balloon (31).

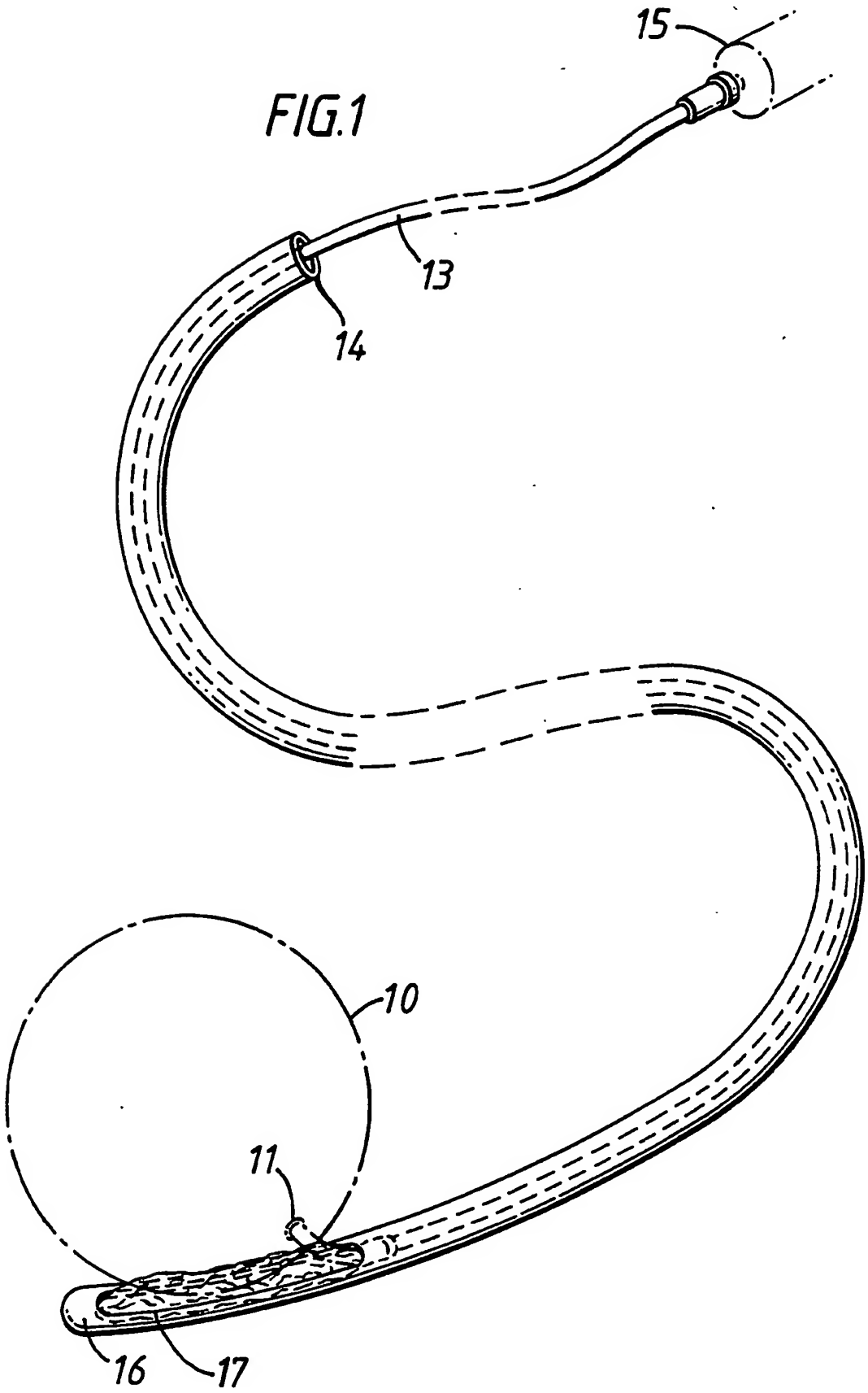
8. Apparatus as claimed in claim 7 characterised in that said gas is carbon dioxide.

9. Apparatus as claimed in claim 7 characterised in that part (36) at least of the wall of the balloon permits injection into the balloon of said another substance for initiation of the gas yielding reaction, yet after such injection seals against efflux of gaseous reaction product from the injection site.

10. Apparatus as claimed in claim 6 characterised in that part at least of the wall surface of the balloon (40) is semi-permeable and in that the balloon contains a substance (41) which has the capacity to absorb in large quantity such water or gastric fluid which passes through said permeable wall.

11. Apparatus as claimed in claim 1 or 6, characterised in that the balloon is of piriform or ellipsoidal shape.

FIG.1



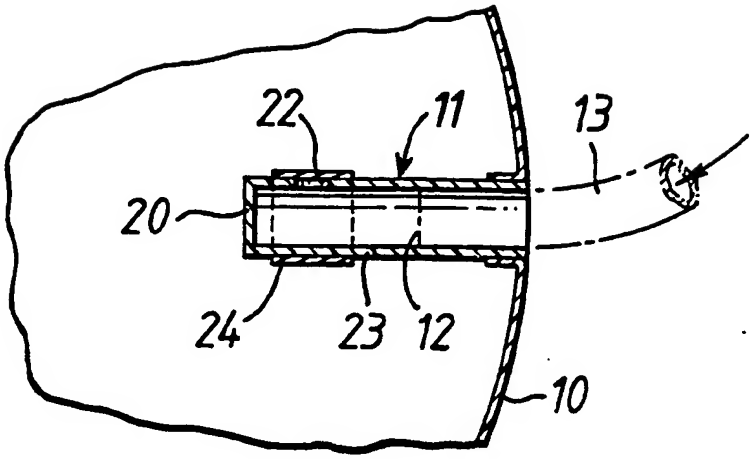


FIG. 2

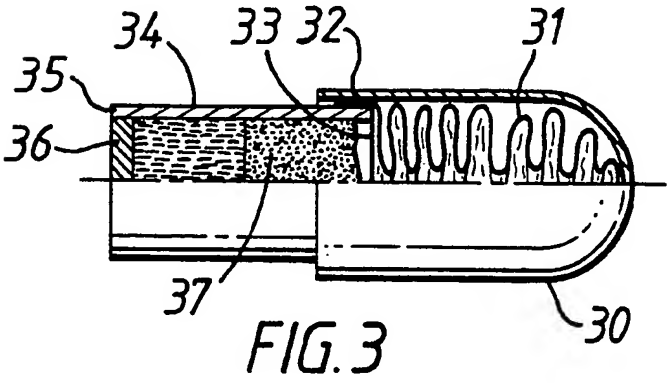


FIG. 3

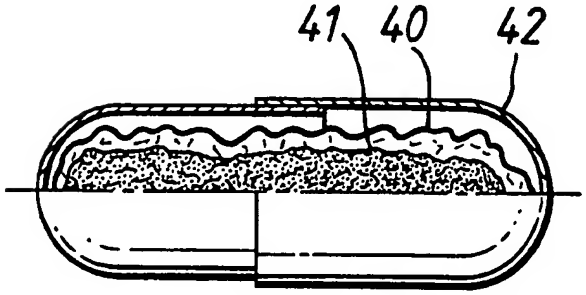


FIG. 4